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09/535,390	03/24/2000	Balaram Ghosh	U 012673-3	2390

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EXAMINER	
KWON, BRIAN YONG S	
ART UNIT	PAPER NUMBER
1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/535,390	GHOSH ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-25* is/are pending in the application.

4a) Of the above claim(s) *2-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of applicant's filing of an amendment on November 26, 2007. By the amendment, claims 9, 10 and 14 have been amended and claims 18-25 have been newly added.

2. Claims 2-25 are pending in the application, but claims 2-8 were withdrawn from further consideration by Examiner as being drawn to the non-elected invention. Claims 9-25 are currently pending for prosecution on the merits.

3. Applicants' amendments in claims 9, 10, 14 and 19-25 necessitate a new of ground of rejection in this Office Action.

4. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "reducing lethality", does not reasonably provide enablement for "preventing lethality…". The specification does not enable any person skilled in the art to which

it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

This rejection is analogous to the previous rejection of claim 9 mailed 07/24/2007.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The instant claim is drawn to a method for "a method for treatment of LPS induced septic shock conditions in an animal by preventing lethality and by reducing severity of symptoms…".

The American Heritage Dictionary (Second College Edition, 1982) defines the term "prevent" as "anticipate or counter in advance, to keep from happening". The interpretation of the instant claims allows for the complete cure and eradication or total elimination of septic shock lethality.

It is known today that the pathophysiology of septic shock is very complex which involves multitude factors, and there are still currently no effective treatments for septic shock ("Therapy for Septic Shock", 2002, www.invent.ucsd.edu.; "Septic Shock", Standen etl., New England Journal of Medicine, abstract (Book Review), Vol. 343, No. 6, pp. 447-448, 2000).

Thus, it is not understood how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to have the "prevention" or completely cure or eradication effect.

The relative skill of those in the art of pharmaceuticals and the unpredictability of the pharmacy art is high. The specification does not provide any competent evidence or disclosed tests that are highly predictive for the preventive utility of the instant compounds.

The specification provides the effects of cucumin in reducing symptoms of LPS-induced septic shock including shivering, lethargy, fever and watery eyes in mice, reducing infiltration of leukocytes in liver, in vitro, and reducing adhesion of neutrophils to endothelial cells in vitro (Examples 7-9). However, there is no demonstrated correlation that the tests and results apply to the claimed preventive utility embraced by the instant claims.

Since the efficacy of the claimed compound(s) in preventing septic shock lethality mentioned above cannot be predicted from a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to use the invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 18-19 and 24-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18 and 19 recite the limitation "said animal". However, there is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 14-16, 18 and 24 are rejected under 35 U.S.C.102(b) as being anticipated by Chantimaa et al. (JP 11-246398A).

Chantimaa teaches use of cucrumin for the treatment or prevention of disease caused by an increase of lipid perioxide in an animal wherein said curcumin is administered to said animal including human, in ranges from 0.1mg-5g/kg, preferably 1m-2g/kg, in various dosage regimen including the delivering of the specified amounts of drug in multiple times and various dosage forms including emulsion, syrup, parenteral injection, tablet and capsule, alone or in combination with other active ingredients including antioxidants such as tocopherol, flavonoid and catechin (abstract and para. [0014-0021]).

Although Chantimaa is silent about “controlling neutrophil infiltration” or “preventing lethality of lipopolysaccharide induced septic shock”, such properties or characteristics must be inherently presented in the referenced method since both the instant application and the referenced teaching are drawn to an administration of same compound or composition to “an animal” in the overlapping concentration.

With respect to the claimed prophylactic ("preventing") utility, applicant's attention is directed to Ex parte Novitski 126 USPQ 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a haec verba recitation for such prophylactic utility. In the instant case, as in Ex parte Novitski, the claims are directed to preventing a malady or disease with old and well known compounds of compositions. The prior art administering compounds inherently possessing a protective utility anticipates claims directed to such protective use.

In re Robertson (1999): "Anticipation under 35 U.S.C.S. § 102(e) requires that each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference…If the prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is "inherent" in its disclosure.

Schering Corp. v. Geneva Pharms., Inc (2003): In the context of determining the validity of a patent, inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure. Where the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results. Inherency, like anticipation itself, requires a determination of the meaning of the prior art. Thus, a court may consult artisans of ordinary skill to ascertain their understanding about subject matter disclosed by the prior art, including features inherent in the prior art. A court may resolve factual questions about the subject matter in the prior art by examining the reference through the eyes of a person of ordinary skill in the art, among other sources of evidence about the meaning of the prior art.

8. Claims 9, 18 and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Aggarwal (WO 97/09877).

Aggarwal teaches a use of curcumin in treating pathology conditions associated with activation of transcription factor NF-kB, such as septic shock, by inhibiting activation of NF-κB, wherein said curcumin is administered in a dose of from about 1mg/kg to about 100mg/kg (page 1, line 21 thru page 2, line 2; page 2, lines 13-15; Claims 1 and 3). Aggarwal lists liposaccharide (LPS) as one of well-known activator of transcription factor NF-κB (page 14, line 13 and 26, see particularly the Aggarwal's cited reference No. 38, Gen, et al., J. Immuno., 1993, 151, 2710-2719 for your reference).

Although Aggarwal is silent about the underlying mechanism of "controlling neutrophil infiltration…" or "by preventing lethality…", such properties or characteristics must be inherently presented in the referenced method since the prior art method employs the same compound (i.e., curcumin) in the overlapping concentration to same treatment population (e.g., an animal) for the same ultimate purpose (treatment of septic shock). It is noted to applicants that the prior art directing the administration of same compound inherently possessing a therapeutic effect for the same ultimate purpose as disclosed by Applicants anticipates the claimed invention even absent explicit recitations of the underlying mechanism.

With respect to the claimed prophylactic ("preventing") utility, applicant's attention is directed to Ex parte Novitski 126 USPQ 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a haec verba recitation for such prophylactic utility. In the instant case, as in Ex parte Novitski, the claims are directed to preventing a malady or disease with old and

well known compounds of compositions. The prior art administering compounds inherently possessing a protective utility anticipates claims directed to such protective use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 9-16, 18 and 20-25 are rejected under 35 USC 103(a) as being unpatentable over Aggarwal (WO 9709877) in view of Ammon et al. (US 5401777), and further in view of Nerenberg et al. (USP 6498147) and Hawiger et al. (USP 6495518).

Aggarwal teaches a use of curcumin in septic shock (which is a pathological condition caused by systemic lipopolysaccharide exposure), by inhibiting activation of NF-κB, wherein said curcumin is administered in a dose of from about 1mg/kg to about 100mg/kg (page 1, line 21 thru page 2, line 2; page 2, lines 13-15; Claims 1 and 3). Aggarwal lists liposaccharide (LPS) as one of well-known activator of transcription factor NF-κB (page 14, line 13 and 26, see

particularly the Aggarwal's cited reference No. 38, Gen, et al., J. Immuno., 1993, 151, 2710-2719 for your reference). However, Aggarwal is silent about (i) step of administering of said curcumin to an animal to "reduce neutrophil infiltration from blood vessels to underlying tissues", (ii) oral administration, specifically "orally as a suspension in pharmacologically acceptable non-toxic organic solvent or oil"; (iiI) the specific time intervals; (iv) "observing every two or three hours for septic shock"; (v) "probing reduction in neutrophil infiltration from blood vessels to the underlying tissue by staining and microscopically examining the extent of inflammation ", and/or (vi) "reducing severity of symptoms of liposaccharide induced septic shock".

Ammon teaches an oral dosage form of curcumin including suspension wherein the oral dosage form is prepared in non-toxic organic solvent or oil (abstract; column 7, lines 3-34).

Nerenberg and Hawiger are being supplied as supplemental references to demonstrate the routine knowledge at the time of the invention was made that inhibition of NF-kB is useful in the treatment of septic shock associated with the activation of NF-kB, namely LPS-induced septic shock (Examples 3 and 4 of USP'147; column 2, lines 24-29 and Example II Of USP'518).

However, as evidenced by Nerenberg and Hawiger, one having ordinary skill in the art would have recognized that curcumin which is known to be useful in septic shock condition by inhibiting the activation of NF-kB would be useful in treating animal with or in need of LPS-induced septic shock condition. One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same

ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

With respect to determination of the specific delivery dosage form, such as oral dosage forms, it would have been obvious to one having ordinary skill in the art since the claimed oral administration of curcumin is well known in the art as taught by Ammon. The above references in combination make clear that the administration of curcumin for the treatment of inflammatory condition such as septic shock condition is old and well known. The above references in combination also make clear that the administration of curcumin in the oral dosage form is old and well known. One having ordinary skill in the art would have been motivated to make such modification to extend the usage of curcumin in readily available oral dosage form to accommodate patient's preference and needs where the compliance could be improved with effective and well tolerated dosage regimen.

With respect to determination of the specific time intervals, monitoring conditions of animal suffering from septic shock and probing step The prior art does not disclose the required specific time interval and "observing every two to three hours". However, differences in time interval requirements or time periods will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such time periods is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable time periods by routine experimentation.

With respect to the instant "reducing severity of symptoms of lipopolysaccharide induced septic shock", such properties or characteristics must be expected feature of the referenced

method since it is a necessary consequence of what was deliberately intended as to the instantly claimed invention in course of septic shock treatment or sepsis.

The prior art does not disclose the required step of "probing reduction in neutrophil infiltration from blood vessels to the underlying tissue by staining and microscopically examining the extent of inflammation". However, such probing technique will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such probing technique is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the probing technique by routine experimentation.

10. Claim 17 is rejected under 35 USC 103(a) as being unpatentable over Aggarwal (WO 9709877) in view of Schneider (US 6013273), and further in view of Nerenberg et al. (USP 6498147) and Hawiger et al. (USP 6495518).

The teaching of Aggarwal has been discussed in above 35 USC 102(b) rejection.

Schneider et al. (US 6013273) teaches the use of antioxidant in treating septic or endotoxin shock (column 4, lines 51-53).

The teaching of Aggarwal differs from the claimed invention in combination with an antioxidant preparation. To incorporate such teaching into the teaching of Aggarwal, would have been obvious in view of Schneider et al. who teaches the use of antioxidant in treating septic shock.

Above references in combination make clear that curcumin and antioxidant have been individually used for the treatment of septic (or endotoxin) shock. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of

combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. *See In re Kerkhoven, 205 USPQ 1069 (CCPA 1980).*

The above references in combination make clear that he combination of curcumin and antioxidant for the treatment of septic shock is old and well known. One having ordinary skill in the art would have been motivated to do so such that such combination provides enhanced activity in treating septic shock while minimizing adverse effects.

As stated above, the prior art does not disclose the underlying pharmacological mechanism of curcumin in "controlling neutrophil infiltration". However, the fact that the applicant may have discovered a new pharmacological mechanism for curcumin is not considered patentably distinctive over the prior art which are directed to the same therapeutic application (for the treatment of septic shock condition).

Response to Arguments

11. Applicant's arguments filed November 26, 2007 have been fully considered but they are not persuasive.

Applicant's argument takes the position that the result of 70% survival of LPS-challenged mice in the instant specification provides enabling disclosure for the instantly claimed prophylactic utility. Applicant alleges that prevention need not be complete cure or eradication and there is no requirement that the prevention must be 100% effective.

Applicant's argument is not found persuasive. Although the specification discloses "70% survival of LPS-challenged mice", the result is not commensurate with scope with these claims

which encompasses curing or complete eradication effects of the curcumin. Thus, the examiner maintains the rejection of the record. As discussed above, there is no evidence in the art that the administration of curcumin would be effective in curing or completely eliminating the condition caused by systemic exposure to LPS ("Therapy for Septic Shock", 2002, www.invent.ucsd.edu.; "Septic Shock", Standen etl., New England Journal of Medicine, abstract (Book Review), Vol. 343, No. 6, pp. 447-448, 2000). Thus, one of ordinary skill in the art would not have known how to use the invention commensurate in scope with the instant prophylactic utility, without undue amount of experimentation.

The examiner acknowledges that the Office does not require the present of (all) working examples to be present in the disclosure of the invention (see MPEP 2164.02). However, given the highly unpredictable state of the art and furthermore, given that the applicant does not provide sufficient guidance or direction as to how to make and use the full scope of the presently claimed invention without undue amount of experimentation, the Office would require appropriate disclosure, in the way of scientifically sound reasoning or the way of concrete examples, as to why the data shown is a reasonably representative and objective showing such that it was commensurate in scope with and, thus, adequately enables, the use of the elected species for the full scope of the presently claimed subject matter. Absent such evidence or reasoning, applicant has failed to obviate the rejection of the instant claims under 35 USC 112, first paragraph (for the lack of scope of enablement).

In response to the applicant's argument that there is no correlation between in vitro experiments taught in Aggarwal and a practical utility in currently available form for humans or

animals, the examiner recognizes that the issue of "correlation" is dependent on the state of the prior art. In other words, if the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless there is contradicting evidence that the model does not correlate. As evidenced by Nerenberg et al. (USP 6498147), Hawiger et al. (USP 6495518) and Merlos Roca (WO 99/61030 which is equivalent to USP 6414025), at the time of the invention was made, it was known that NF-kB activation is involved in pathophysiology of septic shock; inhibition of NF-kB activation is useful in the treatment of septic shock; LPS induces NF-kB activation; and inhibitor of NF-kB activation is useful in the treatment of LPS-induced septic shock condition. Thus, one skilled in the art would have recognized that there is reasonable correlation between the disclosed in vitro utility and an in vivo activity, and therefore a rigorous correlation is not necessary where the disclosure of pharmacological activity is reasonable based upon the state of art at the time of the invention was made. Again, the examiner determines based on ponderous evidences from the prior art that it is enough to rely on in vitro studies where, as here, a person having ordinary skill in the art has basis for perceiving those studies as constituting recognized screening procedures with clear relevance to utility in humans or animals.

In response to applicant's argument that Aggarwal does not teach that curcumin would be effective in the treatment of septic shock which is a "inflammatory conditions caused by systemic expousre of lipopolysaccharide" per se even though it is stated to be useful in the treatment of pathological conditions associated with activation of transcription factor NF-kB,

such as septic shock, by inhibiting activation of NF-κB , the examiner recognizes that proof of efficacy is not required for prior art reference to be enabling for purposes of anticipation under 102. That is, a section 102 prior art reference does not have to be "effective" to be enabling and thus anticipating. Thus, the examiner maintains the rejection of record. Anticipation under 35 USC 102 is an essentially irrebuttable question of fact, wherein the court stated that anticipation "cannot be overcome by evidence of unexpected results or teachings away in the art". *In re Malagari, 499 F.2d 1289, 182 USPQ; In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In re Fracalossi, 681 F.2d 792, 215 USPQ 569 (CCPA 1982); In re Alternpohl, 500 F.2d 1151, 183 USPQ 38 (CCPA 1974); In re Wiggins, 488 F.2d 538, 179 USPQ 421 (CCPA 1973); In re Wilder, 429 F.2d 447, 166 USPQ 545 (CCPA 1970).* Indeed, a reference might reside in a nonanalogous art and yet constitute an anticipation of a claimed invention under 35 USC 102. *In re Self, 571 F.2d 134, 213 USPQ 1 (CCPA 1982).*

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). The fact that the applicant may have discovered a new pharmacological mechanism for curcumin in "controlling neutrophil infiltration" or "reduces neutrophil infiltration from blood vessels to underlying tissues" is not considered patentably distinctive over the prior art which are directed

to the same therapeutic application (for the treatment of septic shock condition). Thus, the references in combination makes obvious the instant invention.

Relevant Art of Record

12. The prior art made of record and not relied upon is considered pertinent to applicant's invention. Geng et al. (J. Immunol., 1993, 151, pp. 6692-6700) discloses that LPS induces activation of transcription factor NF-κB (abstract; page 6698, column 2, second paragraph); Merlos Roca (WO 99/61030 or USP 6414025) discloses the use of inhibitor of NF-kB for the treatment of pathologies associated with the activation of NF-kB including septic shock (abstract; column 3, lines 43-44).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. No Claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614